IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC., Plaintiff, v. APOTEX, INC., Defendant.	)	C.A. No. 06-230 (GMS)

MERCK'S ANSWERING BRIEF IN OPPOSITION TO APOTEX'S MOTION FOR LEAVE TO SUBSTITUTE CORRECTED EXHIBITS TO ITS PENDING MOTION FOR LEAVE TO AMEND

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Plaintiff Merck & Co., Inc. opposes Apotex, Inc.'s Motion for Leave to Substitute ("motion to substitute") Corrected Exhibits to its pending Motion for Leave to Amend to File Its Proposed First Amended Answer, Affirmative Defenses, and Counterclaims ("motion for leave"). Apotex seeks to substitute a new proposed counterclaim ("Second Proposed Counterclaim" or "SPC") for its originally proposed counterclaim ("First Proposed Counterclaim" or "FPC"). But under Rule 16(b), Apotex has not shown good cause to modify the Scheduling Order to permit the filing of its untimely Second Proposed Counterclaim, and in any event under Rule 15(a) the Second Proposed Counterclaim is as futile as the First. Finally, while Apotex represents that it wishes to "correct" allegations it has "learned" are untrue, it withholds critical information from the Court and continues nonetheless to perpetuate the untrue allegations in its new proposed pleading. Simply put, Apotex seeks in bad faith to prolong a case where the Court does not even have subject matter jurisdiction.

NATURE AND STAGE OF THE PROCEEDINGS[1]

Merck filed this suit for infringement of nine Merck patents based upon its receipt of a letter from Apotex stating it had taken the infringing act of filing a "paragraph IV" certification with an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Merck's FOSAMAX® tablets. FPC ¶ 14; *see* Opp. Mtn. for Leave, Ex. A. Before filing suit, Merck twice requested access to "all relevant information" from Apotex's ANDA. *See* Opp. Mtn. for Leave at n.1 & Exs. B-D. By its own admission, however, Apotex did not provide any requested information to Merck. FPC ¶ 57. Merck therefore filed its complaint on

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[1] Merck has described these proceedings more fully in its Answering Brief in Opposition to Apotex's Motion for Leave to File a First Amended Answer, Affirmative Defense and Counterclaims filed November 7, 2006 ("Opp. Mtn. for Leave") (D.I. 38), to which the Court should refer for further details. *See* Opp. Mtn. for Leave at 1-6 & nn.2-6.

April 7, 2006. D.I. 1. A month later Apotex finally provided Merck confidential excerpts of its ANDA "to resolve this matter." FPC ¶ 57. After reviewing these excerpts, Merck notified Apotex that it would grant an unconditional covenant not to sue on the patents-in-issue and, on August 7, 2006, sent Apotex a copy of its covenant not to sue. *Id.* ¶ 59; D.I. 15 (Ex. C).

At the August 8, 2006 scheduling conference, Apotex indicated it would contest dismissal, despite the covenant not to sue. D.I. 16 (Ex. D at 3-4). At the conference, the Court set a deadline of October 13 for the amendment of pleadings. Minute Entry, August 8. A week later Merck filed a motion to dismiss this action as moot, on the ground that under governing precedent the Court no longer enjoyed subject matter jurisdiction due to Merck's conveyance of the unconditional covenant not to sue. D.I. 15. That motion is fully briefed and decisional. On August 29, the Court issued a Scheduling Order reiterating that amended pleadings were due by October 13. On October 13, the last possible day it could do so, Apotex filed its motion for leave to file its First Proposed Counterclaim. D.I. 28. Some weeks later, on November 3, Apotex then filed its motion to substitute the Second Proposed Counterclaim for the First. D.I. 36. Merck filed its opposition to Apotex's original motion to leave on November 7. D.I. 38.

STATEMENT OF FACTS

Apotex's First Proposed Counterclaim is based on allegations that Merck filed suit allegedly knowing its infringement allegations were objectively baseless so it could then provide a covenant not to sue and dismiss the suit without an adverse decision on the merits, allegedly with the intent and effect of postponing the date on which Apotex might potentially obtain approval for its ANDA for a generic version of FOSAMAX®. *See* FPC ¶¶ 1, 32-42, 48-56. Apotex alleges specifically that Merck's lawsuit was "objectively baseless" when filed because Merck "knew" that the asserted patent claims "were invalid and/or not infringed by Apotex's proposed alendronate sodium product *as set forth in Apotex's ANDA*." *Id.* ¶¶ 54, 56 (emphasis

added). At the core of these conclusory allegations is Apotex's assertion of "willful blindness" on Merck's part: that Merck refused a pre-suit offer to review Apotex's confidential ANDA, which allegedly would have demonstrated to Merck that its patent suit could not be brought. *See id.* ¶¶ 32-42, 54-56, 69. The only non-conclusory (i.e., factual) allegations made by Apotex to support this "willful blindness" assertion are in paragraphs 38, 39 and 42 of the First Proposed Counterclaim:

> 38. As required . . ., Apotex offered . . . to provide Merck with certain confidential information in order for Merck to determine whether Apotex's ANDA did in fact infringe Merck's patents, notwithstanding Apotex's paragraph IV certification, prior to Merck's filing an infringement lawsuit.
>
> 39. In response to Apotex['s] offer . . ., Merck did not request that Apotex provide any information to it for its determination of infringement.
>
> 42. If Merck had any doubt as to the assertions Apotex made in its paragraph IV certifications, Merck could have requested that Apotex provide it with certain confidential information from Apotex's ANDA . . . so that it could determine whether Apotex's ANDA would infringe any of Merck's patents at issue.

As Merck showed in its Answering Brief in opposition to Apotex's motion for leave, the allegations in paragraphs 39 and 42 are demonstrably false; contrary to these allegations, Merck sent two written requests for "all relevant information" from Apotex's ANDA in March 2006 before Merck filed suit (*see* Opp. Mtn. For Leave at 1-2 & n.1 & Exs. A-D), but Apotex did not provide Merck any information from its confidential ANDA until more than a month after Merck filed suit. FPC ¶ 57 ("After Merck filed its complaint . . ., Apotex subsequently provided Merck with certain confidential information from its ANDA in order to resolve this matter.").

Confronted by Merck with these indisputable facts, which have been in Apotex's possession since March 2006, Apotex now seeks to replace its First Proposed Counterclaim with its new Second Proposed Counterclaim, as if the former had never existed and the false allegations contained therein were of no consequence or relevance to the remainder of Apotex's

allegations or the viability of its proposed counterclaim. *See* Mtn. to Substitute at 1 & Exs. A, B. Apotex hopes to "substitute" its new Second Proposed Counterclaim (filed on November 3) for its First Proposed Counterclaim (filed on October 13), and to have the former 'relate back' to Apotex's October 13 motion for leave as if it had been timely filed. Apotex represents that the two pleadings are identical except that in the Second Proposed Counterclaim paragraphs 39 and 42 are removed and the remaining paragraphs renumbered. *Id.* Apotex does not acknowledge the October 13 deadline for pleading amendments, offer any explanation for its failure to file the Second Proposed Counterclaim sooner, or provide any meaningful information about the nature of the proposed revision or the circumstances giving rise to its request to make that revision. *See id.* at 1-2. Instead, Apotex characterizes the deletion of these key allegations as a "correction" and represents that it did not "learn" of the facts requiring the "correction" until November 1. *Id.*

SUMMARY OF ARGUMENT

Apotex's motion to substitute should be denied for at least three reasons.

First, Apotex fails to show good cause under Rule 16(b) to modify the Court's Scheduling Order so as to permit it to file its untimely Second Proposed Counterclaim. By seeking "substitution" Apotex wants the Court to treat the Second Proposed Counterclaim as if Apotex had filed it on October 13, the deadline for amended pleadings under the Court's Scheduling Order, but in fact Apotex did not file its newest proposed counterclaim until November 3, and consequently Apotex must establish good cause under Rule 16(b) to modify that Order, which it fails to do.

Second, Apotex's motion should be denied under Rule 15(a) because the Second Proposed Counterclaim, like the First, is futile. Just as with the First Proposed Counterclaim, Apotex cannot show antitrust injury or standing. Moreover, in the First Proposed Counterclaim, Apotex's "sham" litigation claim was one of "willful blindness": essentially that (1) before

filing suit, a reasonable litigant would have reviewed the confidential information Apotex alleges it offered to Merck to analyze infringement, (2) upon reviewing that information a reasonable litigant would have determined that Merck's patents were not infringed by Apotex's proposed generic product as set forth in its ANDA, and (3) Merck's alleged failure to request such information from Apotex following Apotex's offer to provide it shows that Merck knew, or should have known, that its patent infringement allegations were objectively baseless. Apotex's deletion of paragraphs 39 and 42 rips the heart out of that claim. Absent an opportunity to review the information in Apotex's ANDA – an opportunity Apotex ***still*** alleges it provided, despite that when Merck requested the information ***Apotex did not follow through*** – this house of cards collapses.

Third, Apotex's motion should be denied under Rule 15(a) because it has again acted in bad faith by its proposed counterclaim, this time by misleading the Court about the facts underlying Apotex's requested substitution and its purported "discovery" of those facts. Given Apotex's undisputed knowledge of Merck's two letters in March, the allegations of paragraphs 39 and 42 reflect at worst misrepresentation and at best recklessness. Yet now, Apotex seeks to gloss over the magnitude of this by (a) misrepresenting that it just "learned" those allegations "were not correct" on November 1 and (b) failing to explain in what manner the incorrect allegations were relevant to its proposed counterclaims. Apotex would stealthily slip the erroneous paragraphs out and sweep them under the rug as if they were simply unnecessary surplusage in the First Proposed Counterclaim rather than the linchpin of Apotex's "sham" lawsuit assertion. And while Apotex now seeks to delete these two false paragraphs, the Second Proposed Counterclaim remains laced with still other allegations pregnant with the same suggestion of the deleted allegations, falsely suggestive of the deleted facts, and otherwise

untenable in the absence of the deleted allegations.

ARGUMENT

I. LEGAL STANDARDS UNDER RULES 16(B) AND 15(A)

Rule 16(b) "governs amendment of pleadings once a scheduling order has been entered," *Hutchins v. United Parcel Service, Inc.*, 2005 U.S. Dist. LEXIS 15625, at *8 (D. N.J. July 26, 2005), and "provides that a pretrial scheduling order 'shall not be modified except upon a showing of *good cause* and by leave of the district judge. . . .'" *Gonzalez v. Comcast Corp.*, 2004 U.S. Dist. LEXIS 17896, at *2 (D. Del. Aug. 25, 2004) (quoting Fed. R. Civ. P. 16(b)). "Good cause depends on the diligence of the moving party [and showing] that despite its diligence, it could not reasonably have met the scheduling order deadline." *Hutchins*, 2005 U.S. Dist. LEXIS 15625, at *8; *Gonzalez*, 2004 U.S. Dist. LEXIS 17896 at *2-3. "[T]he absence of prejudice to the nonmovant is not a consideration under the good cause standard." *Id.* (citing *Globespanvirata, Inc. v. Tex. Instruments, Inc.*, 2005 U.S. Dist. LEXIS 16348, at *9 (D. N.J. July 12, 2005)).

Under Rule 15(a), "leave to amend need not be granted when amending the complaint would clearly be futile." *Cowell v. Palmer Twp.*, 263 F.3d 286, 296 (3d Cir. 2001). "In assessing 'futility,' the district court applies the same standard of legal sufficiency as applies under Rule 12(b)(6)." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997).[2] In addition, an amendment should not be allowed where there has been "bad faith on the part of the [movant]." *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004).

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[2] As set forth in Merck's Answering Brief to the motion for leave, familiar Rule 12 standards teach that the Court is not required to accept as true "unsupported conclusions," "bald assertions," or "self-evidently false" allegations. Similarly, legal conclusions draped in the guise of factual allegations may not benefit from the presumption of truthfulness. *See* Merck's Opp. to Mtn. for Leave at 9-10 & n.9.

II. APOTEX'S MOTION TO SUBSTITUTE SHOULD BE DENIED BECAUSE APOTEX FAILS TO SHOW GOOD CAUSE TO MODIFY THE SCHEDULING ORDER

"'[S]cheduling orders are the heart of case management [and cannot] be flouted.'" *Globespanvirata*, 2005 U.S. Dist. LEXIS 16348, at *10 (quoting *Turner v. Schering-Plough Corp.*, 901 F.2d 335, 341 n.4 (3d Cir. 1990)). Apotex's belated November 3 filing of its motion to substitute its Second Proposed Counterclaim flouts the Court's Scheduling Order, which imposed an October 13 deadline for amendments to pleadings. By styling its request as a "motion to substitute corrected exhibits" Apotex wants the Court to treat the Second Proposed Counterclaim as filed with its motion for leave on October 13, but Apotex's pretense that the Second Proposed Counterclaim is merely a "corrected exhibit" does not change the fact that it is a proposed amended pleading that was not filed by the required deadline. Since Apotex's Second Proposed Counterclaim was untimely under the Scheduling Order, Apotex is obliged to establish "good cause" to modify that Order. *Hutchins*, 2005 U.S. Dist. LEXIS 15625, at *8 (citing *Eastern Minerals & Chems. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000)).

To establish good cause, Apotex "must show that despite its diligence, it could not reasonably have met the scheduling order deadline." *See id.* (internal citation omitted). Apotex has not even attempted to make such a showing. Apotex (1) does not acknowledge the October 13 Scheduling Order deadline, (2) does not acknowledge its resulting burden to establish Rule 16(b) good cause for modification of that Order, (3) does not provide a meaningful explanation for its request to file the Second Proposed Counterclaim after the deadline, (4) does not set forth any facts to establish diligence, and (5) does not even *claim* to have acted diligently. Apotex's sole statement of the timing and necessity of its requested "substitution" is that "[o]n November 1, 2006, Apotex learned that [paragraphs 39 and 42] in its First Amended . . . Counterclaims . . . contained allegations that were not correct." Mtn. to Substitute at 1. Even if this cursory

statement were true – and as demonstrated below, it is not – it would be insufficient for good cause. *See Koplove v. Ford Motor Co.*, 795 F.2d 15, 18 & n.2 (3d Cir. 1986) (one "must provide … a record which affirmatively demonstrates, with specificity, diligent efforts on his or her part and unusual circumstances which have frustrated those efforts").

In addition, Apotex did not "learn" of the facts requiring "correction" of its proposed counterclaim on November 1, as it claims. Rather, it has known all along that in March 2006 Merck sent two letters asking for its confidential ANDA information. Opp. Mtn. for Leave, n.1 & Exs. A-D. Those letters were in Apotex's possession when it filed the false allegations of the First Proposed Counterclaim. In fact, Merck's letters were directed to the individual appointed by Apotex in its paragraph IV certification letter to receive a request for confidential ANDA information. *See id.* Exs. A, B, D. Apotex even responded to one of Merck's two letters. *See id.* Ex. C. Thus, Apotex knew of Merck's request and either (a) was content to allow its counsel (unknowingly perhaps) to make these misrepresentations to beef up its tenuous proposed counterclaim, or (b) at best, acted recklessly to review the evidence before making these critical allegations. Whichever, Apotex failed to confirm the Rule 11 basis for its First Proposed Counterclaim and thus has destroyed any prospect of showing diligence.[3]

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[3] Notably, Apotex waited until October 13 – the last permissible day – to file its First Proposed Counterclaim, despite having possession of all facts pertinent to that pleading since at least August, when Merck conveyed the unconditional covenant not to sue that purportedly gave rise to Apotex's proposed antitrust counterclaim. Apotex's need for "correction" after the deadline is thus attributable entirely to its own doing. Its failure to accurately state the evidence in its possession, its eleventh-hour motion for leave to amend, and its untimely effort to "correct" imprudently made allegations, all lead to one conclusion: Apotex cannot show diligence or good cause, but only "self-inflicted wounds." *See Mobley v. City of Atlantic City*, 1999 U.S. Dist. LEXIS 21121, at *12 (D. N.J. June 24, 1999) ("Where a party chooses to disregard the reasonable scheduling orders of [the] court, it does so at its peril . . . [and] '[a]ny prejudice . . . suffered therefrom result[s] from a self-inflicted wound.").

Finally, that "Merck will not be prejudiced by the filing of this corrected version," Mtn. to Substitute at 2, is both irrelevant and incorrect. "The absence of prejudice to the nonmovant is not a consideration under the good cause standard." *Hutchins*, 2005 U.S. Dist. LEXIS 15625, at *8. Further, the costs and delay occasioned by Apotex's moving-target effort to do whatever may be necessary to maintain this case in spite of Merck's covenant not to sue *is* prejudicial to Merck. For the reasons set forth in Merck's motion to dismiss and its Answering Brief to Apotex's motion for leave, this case should be dismissed for lack of subject matter jurisdiction. It is only Apotex's continuing futile efforts to gin up a controversy to sustain this case.

III. APOTEX'S MOTION TO SUBSTITUTE SHOULD BE DENIED BECAUSE THE SECOND PROPOSED COUNTERCLAIM IS AS FUTILE AS THE FIRST

Merck has already demonstrated in its Answering Brief to Apotex's motion for leave that Apotex's First Proposed Counterclaim is futile for want of injury in fact, antitrust injury, and standing. *See* Opp. Mtn. for Leave at 10-32. Apotex's deletion of paragraphs 39 and 42 does not have any effect on the analysis Merck articulated on these issues, and accordingly, Merck will not repeat that discussion here. Merck has also already demonstrated in that Answering Brief that Apotex's proposed counterclaim is futile because it has not alleged, and cannot allege, any well pleaded facts to support its claim that Merck's suit was "objectively baseless" when filed and thus within the "sham litigation" exception to *Noerr-Pennington* immunity for litigation activity. *See id.* at 33-38. However, since Apotex's proposed deletion is material to its ability properly to allege a "sham," Merck reprises in part that discussion in the following sections.

A. Apotex Must Allege Specific Non-Conclusory Facts to Overcome Merck's *Noerr-Pennington* Immunity

To strip a defendant of *Noerr-Pennington* immunity, an antitrust plaintiff must show that the suit is a "sham" by demonstrating that (1) "the *lawsuit* must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits"; and (2) "the

baseless *lawsuit* conceals an attempt to interfere directly with the business relationships of a competitor, through the use of governmental process – as opposed to the outcome of that process – as an anti-competitive weapon." *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 122-23 (3d Cir. 1999) (quoting *Professional Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49, 60-61 (1993) ("*PRE*") (emphasis added)). "[O]nly if challenged *litigation* is objectively meritless may a court examine the litigant's subjective motivation." *Id.* (emphasis added).

Patent litigation will not be considered a sham so long as a "reasonable litigant" could believe that "at least *one claim* in the lawsuit has objective merit." *Dentsply Int'l v. New Tech. Co.*, 1996 U.S. Dist. LEXIS 19846, at *7-9 (D. Del. Dec. 19, 1996) (emphasis added). Therefore, for Apotex to succeed in circumnavigating Merck's *Noerr-Pennington* immunity and adequately allege Merck's lawsuit a "sham," Apotex must sufficiently allege facts that show that an objectively reasonable litigant in Merck's circumstance would have concluded that *each and every asserted claim* of Merck's nine patents were invalid or not infringed. That is, it is not sufficient for Apotex to allege facts that a reasonable litigant would have concluded that a particular claim of a particular patent is invalid or not infringed; Apotex must allege facts showing that such litigant would have concluded that *not a single claim of any of the nine patents* is valid and infringed.

A party attempting to invoke the "sham" exception must plead specific non-conclusory facts to survive a motion to dismiss. Under the Rule 8 pleading standard, "in any case, whether antitrust or something else, where a plaintiff seeks damages or injunctive relief, or both, for conduct which is prima facie protected by the First Amendment, the danger that the mere pendency of the action will chill the exercise of First Amendment rights requires more specific allegations than would otherwise be required." *City of Newark v. Delmarva Power & Light Co.*,

497 F. Supp. 323, 326 (D. Del. 1980) (quoting *Franchise Realty Interstate Corp. v. San Francisco Local Joint Executive Bd.*, 542 F.2d 1076, 1082-1083 (9th Cir. 1976)). "Rule 8 does not require a detailed statement of facts, but it does require a plain statement showing entitlement to relief, not conclusions of law, like 'misusing and abusing' and 'sham, false and misleading' . . . . Such conclusory phraseology begs the question." *Outboard Marine Corp. v. Pezetel*, 474 F. Supp. 168, 173 (D. Del. 1979) (citing *Franchise Realty*, 542 F.2d at 1079).[4] Thus, the "antitrust pleader who fails to allege circumstances indicating that the suit against him is clearly within the *Noerr* 'sham exception' must expect his claim to fail at the outset." *City of Newark*, 497 F. Supp. at 327.

B. Merck Was Entitled to File Suit Following Apotex's Failure to Disclose Information Demonstrating Non-Infringement

A patentee has the right to enforce its presumptively valid patents and to test an alleged infringer's contentions that that the patents are invalid or not infringed. *First Graphics, Inc. v. M.E.P. Cad, Inc.*, 2002 U.S. Dist. LEXIS 14914, at *8 (N.D. Ill. Aug. 13, 2002) (patentee need not accept opponent's unsupported assertion that patentee's case lacks merit); 35 U.S.C. § 282 ("A patent shall be presumed valid"). In the patent litigation context, "[t]he Federal Circuit has interpreted Rule 11 to require, 'at a minimum, that an attorney interpret the asserted patent claims and compare the accused device with those claims before filing a claim of infringement.'" *Arrival Star, Inc. v. The Descartes Systems Group, Inc.*, 2004 U.S. Dist. LEXIS 22433, at *30 (S.D.N.Y. Nov. 8, 2004) (quoting *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1300-

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[4] *See also Spanish International Communs. Corp., SIN, Inc. v. Leibowitz*, 608 F. Supp. 178, 184 (S.D. Fla. 1985) ("talismanic phraseology" insufficient to allege "sham"); *Zachair, Ltd. v. Driggs*, 965 F. Supp. 741, 749 (D. Md. 1997) (nakedly labeling suit "objectively baseless" insufficient).

01 (Fed. Cir. 2004)).[5] "The Federal Circuit has held that where a patentee has requested information concerning purportedly infringing products and that request has been rebuffed or rejected by the party subsequently named a defendant, the filing of a lawsuit [is] not sanctionable." *Id.* at *35-36 (citing ***Hoffmann La Roche, Inc. v. Invamed Inc.***, 213 F.3d 1359, 1363-65 (Fed. Cir. 2000) (patentee conducted reasonable pre-suit inquiry where before suit it attempted to ascertain whether drug maker's manufacturing processes were infringing but could not do so)).

The undisputed facts show that Apotex has no support for its mere conclusory allegations that Merck's lawsuit is a "sham." The paragraph IV certification in Apotex's ANDA was an act of infringement as a matter of law. *See* 35 U.S.C. § 271(e)(2)(A). Under the structure of Hatch-Waxman, and before filing suit, Merck rightly requested access to confidential information in Apotex's ANDA to determine whether the proposed generic product would infringe Merck's patents. Apotex, however, failed to provide that information or other information (besides a self-serving letter) to establish the proposed composition of its generic tablets as exactly described in the ANDA. *See* Opp. Mtn. for Leave, n.1 & Exs. A-D; SPC ¶ 55. Since Merck requested information concerning the potentially infringing product and Apotex failed to produce it, Merck's filing of this suit was reasonable as a matter of law. *See Hoffmann*, 213 F.3d at 1363-65 (pre-suit investigation was reasonable where "at the end of [such] it had neither evidence of infringement nor non-infringement"); *Arrival Star*, 2004 U.S. Dist. LEXIS 22433, at *35-36.[6]

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[5] "The courts have declined to impose any special, pre-filing investigation requirements upon the plaintiff in patent cases independent of Rule 11." *Id.* (citing Federal Circuit authorities).

[6] The reasonableness of Merck's pre-suit investigation is buttressed by the fact that it was constrained by the Hatch-Waxman Act's requirement that Merck file suit within 45 days of Apotex's paragraph IV letter or lose the right to obtain a stay of FDA approval. *See* Opp. Mtn for Leave at n.3 (cases).

Apotex complains of a "self-inflicted wound." *See Hoffman* , 213 F.3d at 1364 (if defendant "initially had told [plaintiffs] … the process used to manufacture the drug – as it subsequently did – it could have avoided … litigation and the expenses incurred in defending it").

C. Apotex's Conclusory Allegations That Merck Knew Its Patents Were Invalid Or Not Infringed Are Insufficient to Plead Objective Baselessness

In exercise of its *Noerr* petitioning rights, Merck's complaint sought a finding of infringement by Apotex of one or more claims of Merck's nine patents in suit. Apotex alleges that Merck's complaint is a "sham" because Merck allegedly knew that the asserted patent claims allegedly are (1) invalid and/or (2) not infringed. As discussed above, one of these two pillars upon which Apotex's "sham" claim is based has crumbled: Apotex's failure to provide information from its ANDA describing the composition of Apotex's proposed generic drug in response to Merck's pre-suit requests destroys Apotex's ability properly to plead that Merck's infringement claims were objectively baseless. Consequently, Apotex's "sham" claim can survive only if Apotex can set forth proper allegations to support the other pillar – invalidity. However, just as the First, Apotex's Second Proposed Counterclaim fails to plead any facts that would indicate that the Court should strip from every one of Merck's nine patents their statutory presumption of validity or – more to the point – that Merck knew or should have known of the alleged invalidity of every one of its nine asserted patents when it filed suit against Apotex. Instead, taking the factual allegations of the Second Proposed Counterclaim at their best, Apotex has but pled the invalidity of two claims of a single Merck patent, the '329, and nothing further. *See* Opp. Mtn. for Leave at 36-38.[7] Apotex's mantra that "[t]he filing of this lawsuit was

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[7] *See also Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1568 (Fed. Cir. 1984) ("Each claim must be presumed valid independently of the validity of any other claim.").

objectively baseless because Merck knew that the claims in the patents it was asserting were invalid" (e.g., SPC ¶ 52) is nothing more than a label without facts, and thus insufficient to invoke the *Noerr* "sham" exception. *See* Opp. Mtn. for Leave at 9-10, n.9, 32-33 & n.18 (cases).

IV. APOTEX'S MOTION TO SUBSTITUTE SHOULD BE DENIED BECAUSE THE SECOND PROPOSED COUNTERCLAIM IS ASSERTED IN BAD FAITH

Apotex's motion to substitute demonstrates again its drive to continue litigation with Merck despite the lack of any controversy. Apotex misrepresents that it first "learned" of the facts requiring the "correction" on November 1. Mtn. to Substitute at 1. As noted above, Apotex possessed the evidence that proves its allegations in the deleted paragraphs to be untrue *for over six months*. Apotex's failure to present these facts honestly shows a lack of good faith.

The manner in which Apotex seeks to revise its Second Proposed Counterclaim also shows a lack of good faith. While Apotex seeks to delete former paragraphs 39 and 42, it has left in place other paragraphs that spring from those very same false allegations and have no factual basis in the absence of those allegations. For example, in paragraph 38, Apotex alleges that

> As required . . ., Apotex offered in its paragraph IV certification to provide Merck with certain confidential information in order for Merck to determine whether Apotex's ANDA did in fact infringe Merck's patents, notwithstanding Apotex's paragraph IV certification, prior to Merck's filing an infringement lawsuit.

In view of Apotex's later allegation that it provided information from its ANDA to Merck only after Merck filed suit (¶ 55), paragraph 38 suggests two false things: that (1) Merck failed to request the information (but Merck did), and (2) if Merck had requested the information, Apotex would have followed through on its offer to provide it (but Apotex did not).

Similarly, the Second Proposed Counterclaim is replete with conclusory allegations that Merck "knew" before filing suit that Apotex's proposed generic "*as set forth in its ANDA*"

would not infringe Merck's patents. *See, e.g.*, SPC ¶¶ 52, 54. Given Apotex's inability to plead facts showing that Merck knew, or had any ability to know, the confidential information contained in its ANDA, and given its concession that Merck asked for that information but Apotex failed to provide it before suit, Apotex's continued allegation that Merck "knew" that Apotex's proposed generic "*as set forth in its ANDA*" was not infringing continues to suggest a false fact, and demonstrates again that Apotex's motion is not offered in good faith.

Finally, the evidence of Apotex's bad faith is amplified by allegations in the Second Proposed Counterclaim showing that, after Merck filed suit, Apotex finally provided information from its ANDA – the same information that in paragraph 38 (above) Apotex alleges was available to Merck before the suit – and that Merck then promptly sought to end this case:

> 55. After Merck filed its complaint …, Apotex subsequently provided Merck with certain confidential information from its ANDA in order to resolve this matter.
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> 56. That information showed that Apotex does not use a formulation that is covered by Merck's patents.
>
> 57. After Apotex provided its confidential information to Merck, Merck indicated that it would present Apotex with a covenant not to sue.
>
> 63. Merck's unilaterally tendered covenant … admits on its face that based upon confidential information provided by Apotex the products that are the subject of Apotex's ANDA for alendronate sodium (1) will not contain anhydrous lactose or hydrous fast flow lactose, and (2) will not contain anhydrous alendronate sodium.

These allegations show that it was Apotex, not Merck, who was responsible for Merck's lack of pre-suit access to the confidential information from Apotex's ANDA, and that once Apotex provided that information (as it should have beforehand) Merck promptly eliminated any controversy from the case by conveying a covenant not to sue.

CONCLUSION

For the foregoing reasons, Merck respectfully requests that the Court deny Apotex's motion for leave to substitute corrected exhibits to its pending motion for leave to amend.

Dated: November 22, 2006

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CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

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Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on November 22. 2006 upon the following individuals in the manner indicated:

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